The iStent® Trabecular Micro-Bypass Stent System is contraindicated under the following circumstances:

- Neovascular glaucoma, because the device would not be expected to work in such situations.
- In eyes with primary angle closure glaucoma (POAG) currently treated with ocular hypotensive medications.
- To reduce intraocular pressure in phakic patients, can enhance the formation or progression of cataract.
- Phakic patients, can enhance the formation or progression of cataract.
- Do not use the devices if the tip of the stent is inserted into the Schlemm’s Canal. Once the stent is in the inserter, it can then be implanted once it has been inserted into Schlemm’s canal. Two model numbers (GTS100L and GTS100R) are available. The last digit of these model numbers (L and R) correlates to a left-flow stent and a right-flow stent. The stent and a right-flow stent. The stent is designed for the right eye. GTS100L is for the left eye, and Model GTS100R is designed for the right eye.

Gluako® Trabecular Micro-Bypass System

Catalogue # Description

GTS100L Left-flow iStent® attached to disposable inserter

GTS100R Right-flow iStent® attached to disposable inserter

HOW SUPPLIED

Each iStent® Trabecular Micro-Bypass Stent System is designed for the right eye. The iStent® Trabecular Micro-Bypass Stent System is sterilized by gamma irradiation.

The expiration date on the device package and blister tray is the sterility expiration date. In addition, there is a sterility expiration date that is clearly indicated on the outside of the unit carton. Sterility is assessed by the Tyvek® lid has been opened or the packaging appears damaged. In such cases, the sterility of the product is indicated on the outside of the carton. This device should not be used past the indicated sterility expiration date.

INDICATIONS FOR USE

The iStent® Trabecular Micro-Bypass Stent System is intended for use in adult patients diagnosed with primary open-angle glaucoma (POAG) currently treated with maximally tolerated medical therapy. The device can be implanted with or without cataract surgery.

CONTRAINDICATIONS

The iStent® Trabecular Micro-Bypass Stent System is contraindicated under the following circumstances or conditions:

- In eyes with primary angle closure glaucoma, or secondary angleclosure glaucoma (e.g., neovascular, etc.).
- Neovascular glaucoma, because the device would not be expected to work in such situations.
- In patients with retrolubetal tumors, choroidal detachments, Sturge-Webner Syndrome or any other type of condition that may cause a reduction in intraocular pressure.

INSTRUCTIONS FOR USE

1. A corneal incision is made and the anterior chamber stabilized to ensure it remains inflated.
2. Place a gonioscope on the cornea and reposition the surgical microscope. Stabilize the trabecular meshwork, then view the trabecular meshwork. The tip of the stent will make a "soft" trephine cut in the trabecular meshwork.
3. The inserter, with the stent attached, is placed through the corneal incision. The inserter is then further advanced across the angle chamber once the surgeon is visual confirmation of stent placement by gonioscopy must verify.
4. Irrigate the anterior chamber with balanced salt solution (BSS) through the iStent tip to remove all viscoelastic. Press down gently on the corneal wound and visual confirmation of the edge of the incision as needed to facilitate complete removal of viscoelastic.
5. Inflate the anterior chamber with balanced salt solution (BSS) to facilitate complete removal of viscoelastic.
6. Ensure that the incision is sealed.

Retrieval of an Implanted Stent

If the surgeon determines that another GTS100R inserter is required to grasp a stent (e.g., the original inserter from the stent system is no longer available or not used), the model number of the device may be used by the surgeon as follows:

- Similar to the initial implant procedure, follow the manufacturer’s location of the iStent using a surgical representative.
- Enter the eye through a clear corneal incision.
- Advance to the location of the iStent, and depress the inserter button to open the inserter jaws.
- While holding down the release button, position the snorkel of the iStent® inserter, and then release the release button to grasp the tip of the stent. Once the stent is in the inserter, it can be implanted as described in Step 4 above, or removed from the eye. Communication should be used when exiting the wound.

WARNINGS/PRECAUTIONS

- For prescription use only.
- This device has not been studied in patients with uveitic glaucoma.
- Patients with concurrent cataract surgery, do not recommend placement of the stents, without concurrent phacoemulsification and IOL placement.
- In ophthalmic patients, can enhance the formation or progression of cataract.
- Do not use the devices if the iStent® lid has been opened or the package appears damaged. In such cases, the sterility of the products may be compromised.
- Stent is MR-Conditional; see MRI Information below.

- Microwave is required prior to use of the iStent System, and consists of three main parts:

  - Disposable inserter
  - Diadic session with Glaukos surgical representative
  - Observation surgical cases by Glaukos representative until implementation proficiency is achieved

- Do not re-use the stent(s) or inserter, as this may result in infection and/or device failure. For intraocular implantation adverse events as shown below under "Potential Complications."

- There are no known compatibility issues with the iStent® and other intraocular devices (e.g., viscoelastic) or glaucoma medications.

- Unused product & packaging may be disposed of in accord- ance with local medical waste policies. Implanted medical devices and
MRI SAFETY INFORMATION

Potential complications
Intended use for non-patent postoperative adverse events may be device-related or non-device related.

Potential intraoperative events are as follows:
- Choroidal hemorrhage or effusion
- Crystalline lens touched by inserter
- Posterior capsular bag rupture, in case of combined cataract surgery
- Protein anterior chamber collapse
- Significant corneal injury
- Significant damage to trabecular meshwork
- Significant hyphaema
- Significant iris damage
- Wanner loss of vitreosity, in case of combined cataract surgery
- Significant corneal complications
- Stent malposition or loose stent inside eye requiring reaquisation

Potential postoperative events are as follows:
- Choroidal compulsion (massive hemorrhage and effusion)
- Chronic hypotony
- Clinically significant cystoid macular edema
- Endophthalmitis
- Flat anterior chamber
- Significant loss of best corrected visual acuity (BCVA)
- Intraocular inflammation (non-postoperative)
- IOL dislocation (in pseudophakic eyes)
- IOL increase requiring management with or intravenous medications or with surgical intervention
- Pupillary block
- Retinal complications (dyslipid, flap tears, detachment, or proliferative vitreoretinopathy)
- Secondary surgical intervention including, but not limited to, the following:
  - Trabeculotomy
  - IOL reposition or removal
  - Stent repositioning or removal
  - Significant corneal complications including, but not limited to, opacification, decompensation
  - Significant damage to the trabecular meshwork
  - Significant hyphaema
  - Significant iris damage
  - Significant loss of best corrected visual acuity (BCVA)
  - Stent dislocation or malposition
  - Stent obstruction

STORAGE REQUIREMENTS

The device should be stored at room temperature (15-30°C).

Static magnetic field of 3-Tesla or less

Non-clinical testing has demonstrated that the iStent Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) is MR-Conditional.

A patient with this device can be safely scanned immediately after implantation in an MR system meeting the following conditions:
- Static magnetic field of 3-Tesla, ONLY
- Maximum spatial gradient magnetic field of 10,000-gauss/cm (4.4 T/cm)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
- First Level Conditional Operating Mode of operation for the MR system
- Use of a transmit/receive RF head coil, ONLY

MR-Related Heating

In non-clinical testing, the device produced a temperature rise of 0.4°C during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in a 3-Tesla/238 MHz MR system (Phillips Achieva, Philips Healthcare, Cleveland, OH) using at transmit/receive RF head coil.

MR system reported, whole body averaged: SAR < 1-W/kg

Artifact Information

In non-clinical testing, the image artifact caused by the device extends approximately 23-mm from the image of the device when using a gradient echo pulse sequence and a 3-Tesla MR system.

LABELING

The following symbols are used on the device packaging:

- ∆ Not for sale
- © Do not re-use
- © Only
- © Tyvek® is a registered trademark of DuPont USA.
- © Glaukos® and iStent® are registered trademarks of Glaukos Corporation.

Glucom® and GTS100® are registered trademarks of Glaukos Corporation.